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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,902	10/19/2001	Jean Weissenbach	R-341894	7144
7590 12/01/2003			EXAMINER	
Norman H Stepno Burns Doane Swecker & Mathis PO Box 1404 Alexandria, VA 22313-1404			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/830,902	WEISSENBACH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 12-30 and 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 31, 32 and 41-71 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 31, 32, 47, 54, 62 and 69-71 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some    \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |                                                                                                               |                                                                             |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>0801</u> | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-71 are pending in the application.

#### ***Election/Restrictions***

Applicant's election with traverse of Group XII in the Amendment filed on 8/11/2003 is acknowledged. The traversal is on the ground(s) that all claims are drawn to a product, the nucleotide sequences and to a process of use of the product, and they share a special technical feature that contributes over the prior art. Applicant further argues that the SPG4 gene is not identified in the Kikuno et al. publication, and this reference fails to teach that mutations of SPG4 gene cause the disease autosomal dominant hereditary spastic paraplegia. Further, Applicant argues that the special technical feature identified by the Examiner is narrowly based on a single chemical structure, and the Examiner has used concepts and terminology of US restriction practice which should not be used under principles of unity of invention. Moreover, Applicant argues that all different SEQ IDs recited in the claims are closely related since they can be used in same way and behave in same way, thus they fulfill the criteria for a proper Markush group and "election of species" is not required. Finally, Applicant asserts that the Examiner does not provide proper reasoning for the lack of unity because the conclusion was reached not based on new prior art but the art cited by IPEA, wherein IPEA found unity of the invention among the entire set of claims based on the same prior art.

The above arguments have been fully considered but are not persuasive for following reasons. 37 CFR 1.499 states: "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such

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requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under § 1.143 and 1.144.” Therefore, the restriction practice can be applied to the national stage application regardless whether the international search authority finds unity of the invention or not.

37 CFR 1.475 d) states: “If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c). In the instant case, the first invention of the category first mentioned is purified and isolated nucleic acid of SPG4 gene, any nucleic acid of at least 15 consecutive nucleotides of the SEQ ID NO:1, 2, 72 or 106, and homologue or variants of these sequences. As discussed in the previous office action, the “special technical feature” or Group I is a nucleic acid of SPG4 gene, a fragment or a homologue. This special technical feature does not make a contribution over the prior art because Kikuno publication has shown such a sequence (whether the reference teaches cloning of SPG4, mutations or its relevance to AD-HSP is irrelevant to this special technical feature). Without a special technical feature that makes a contribution over prior art, the unity of invention is broken.

Applicant’s argument that all SEQ IDs have same use and behave in same way is not well supported. For example, SEQ ID NO:1 is a genomic sequence encoding for SPG4 gene whereas SEQ ID NO:4 is an oligo consists 23 nucleotide. One of ordinary skill in the art would clearly recognize that SEQ ID NO:4 cannot encode SPG4 gene, thus these sequences cannot be expected

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to have same function. In addition, although the nucleic acid sequences of claims 1-40 share certain homology, the sequences are not regarded as being of similar nature because the shared common structure is not a significant structural element. Sharing sequence homology of 15 base pair out of 110 kilo base pair nucleic acid is not considered as a significant structural element. Therefore, neither criteria of section (f)(i)(A) nor (B)(1) or (B)(2) is satisfied. As such, the special technical feature requirement is not met.

The requirement is still deemed proper and is therefore made FINAL.

In the attempt to expedite the prosecution, Groups VI and XII will be rejoined.

Accordingly, claims 1-9, 12-30, 33-40 are withdrawn from consideration for being directed to non-elected subject matter. Claims 10, 11, 31, 32 and 41-71 are currently under examination.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 5). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Objections***

Claims 10, 11, 31, 32, 47, 54, 62, 69 and 71 are objected to for containing non-elected subject matter.

Claim 10, 11, 31 and 32 depend on non-elected claims 1 and 5. Amending the claims such that they are only directed to elected inventions is required.

Claims 47, 54, 62, 69 and 71 recites SEQ ID NO: 4-71. However, Applicant elected SEQ ID NO:1 for examination. Thus, Applicant is required to amend the claims so that they only recite SEQ IDs that are part of SEQ ID NO:1. In addition, Applicants is required to indicate the nucleotide position(s) of SEQ ID NO:1 that each of the SEQ ID corresponds to.

Claim 70 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 55. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11, 31, 32, 41-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 11, 31, 32 and 55-71 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Regarding claims 10, 11 and 31, the omitted steps are: how to identify a mutation in the SPG4 gene and how to diagnose AD-HSP associated with SPG4 gene. The claims recite the use of nucleic acid of claim 1, but, since the claim does not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding claim 32 and 55-71, the omitted steps are: how to diagnose AD-HSP. The claimed method is incomplete because it does not contain a step that refers back to the preamble of the claim.

Regarding claims 41-54, the recitation of “amplifying DNA of the sample using one or more primers to obtain an amplification product” renders the claims indefinite because it is unclear which segment of DNA is amplified.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 10, 41-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Hazan et al (1999, Nature genetics, Vol. 23, page 296-303, IDS reference).

Hazan et al. disclose a method for detecting one or more polymorphisms in the SPG4 gene of a human biological sample by amplifying SPG4 gene, sequencing the amplification product and comparing the sequence of the amplification product with the wild type gene (see

page 298, 1<sup>st</sup> col., 2<sup>nd</sup> paragraph, and page 302, 2<sup>nd</sup> col., 2-4<sup>th</sup> paragraph). Therefore, Hazan et al. disclose the instantly claimed invention.

This rejection is based on a 35 USC 102(a) date availability since the foreign priority document has not been perfected. A certified English translation of the foreign priority document would remove the availability of the reference under 102(a) if all the claimed subject matter is disclosed in the foreign priority document.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER